Carotid Artery Stent Fractures: An Engineer’s Perspective

Kenneth Perry, Ph.D.
ECHOBIO LLC
Bainbridge Island, WA
Affiliation and Disclaimer

- ECHOBIO LLC provides engineering analysis and expert services to clients in the medical device industry. Dr. Perry and ECHOBIO LLC do not have any financial interests related to carotid stents or stent products.
- The data contained in this presentation is provided for illustrative purposes only. Specifically:
  - Device architecture and geometry data does not represent any commercially available product.
  - Boundary condition data does not specifically reflect recommended parameters to be used for evaluating a device.
  - Material limit data are not generally applicable to other cases.
Survey of Carotid Artery Stent Fractures

  - Confirmed fracture within <6 months

  - Confirmed fracture within <6 months

  - Confirmed fracture within <7 months
Mechanical Challenges for Carotid Artery Stents

- Anatomical considerations
  - Geometric tortuosity - bifurcations
  - Stiffness gradients - calcification
- Motion and deformations
  - Twist due to head movement
  - Axial stretching and bending
- Deployment considerations
  - Axial stretching/twisting
  - Multiple overlapping stents

Vos et.al., Endovasc Ther, 2003
Nitinol Material Behavior

- Superelastic material behavior
  - Large recoverable deformations
  - Two phase material response
  - Retained martensite, local plasticity


Perry et al., ASM, 2005

Nitinol Fracture and Fatigue

- Traditional LEFM, EPFM are not applicable to medical devices
  - Small features (~100 microns)
  - Two phase material

- Crack initiation more relevant to material limit characterization and development


Perry et al., SEM, 2007
Material Limit Data for Nitinol

• Configuration specific (wire, tubing, sheet, etc)
• Processing effects
• Loading mode (tension, compression, bending, torsion, etc)
• Mean strain effects
• Test efficiency and statistics
• FEA to correlate deflection/strain

Uniform Radial Fatigue

Pelton, et.al.

400M
Coupled Deformation Modes

0.8%

10M
Crushing Deformation

$\varepsilon_{\text{max}} = 1.3\%$

10k
Evaluation of Total Fatigue Life

<table>
<thead>
<tr>
<th>Load Case</th>
<th>Anticipated Design Cycles</th>
<th>Alternating Strain Limit</th>
<th>Alternating Strain Predicted</th>
<th>Safety Factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radial Fatigue</td>
<td>400M</td>
<td>0.40</td>
<td>0.20</td>
<td>2.00</td>
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<tr>
<td>Twisting Fatigue</td>
<td>10M</td>
<td>1.00</td>
<td>0.70</td>
<td>1.40</td>
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<tr>
<td>Radial and Twist</td>
<td>10M</td>
<td>1.00</td>
<td>0.80</td>
<td>1.25</td>
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<tr>
<td>Crushing</td>
<td>10k</td>
<td>1.50</td>
<td>1.30</td>
<td>1.15</td>
</tr>
</tbody>
</table>

Loading modes may be coupled...

Each fatigue mode will consume some portion of the Total Fatigue Life. Need to consider combinations...
Summary

• Testing to 400M cycles with pulsatile radial loading does not adequately address stent fractures seen clinically
• Comprehensive engineering methodology required to optimize and validate stent designs for the carotid arteries
  – Medical imaging measurement and analysis to define clinically relevant deformations
  – Testing to failure to provide feedback for material limit data and component durability
  – Computer simulations to evaluate impact of deformations against established material limits